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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,922	05/18/2004	William G. Weisburg	GP142-02.UT	5696

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/848,922

Applicant(s)

WEISBURG ET AL.

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 77-80 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21-38 and 77-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>multiple</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-19 and 21-38, in the reply filed on October 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Additionally, Applicants have cancelled claims 40-76 and added claims 77-80. Accordingly, claims 1-39, and 77-80 are pending in the instant application, of which claims 20 and 39 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. Claims 1-19, 21-38 and 77-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-19, 21-38 and 77-80 recite a detection probe for determining the presence of *Trichomonas vaginalis* in a test sample, said probe being up to 100 bases in length and comprising a target binding region which forms a hybrid stable for detection with a sequence contained within a first target sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 4,

Art Unit: 1645

under stringent hybridization conditions, wherein said probe does not form a hybrid stable for detection with nucleic acid derived from *Trichomonas tenax* under said conditions.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "a probe, which forms a hybrid stable with a *Trichomonas vaginalis* target sequence of SEQ ID NO: 1-4, but not *Trichomonas tenax*" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants claims fail to disclose the structural identity of any probe which is capable of forming a stable hybrid with *T. vaginalis*, but not with *T. tenax*. Without disclosure of the particular probes used to form a hybrid with *T. vaginalis*, but not with *T. tenax*, Applicants written description requirement is not deemed to be fulfilled. Furthermore, Applicants have claimed probes of up to 100 bases in length. However,

Applicants disclosure fails to identify the upstream or downstream regions of this fragment, which will have a profound impact on the activity of the probe. Accordingly, the written description of the probe is sufficient only for the identified fragment, i.e., "consisting of."

The instant fact pattern closely resembles that in *Ex parte Maizel*, 27 USPQ2d 1662 (BPAI 1992). In *Ex parte Maizel*, the claimed invention was directed to compounds which were defined in terms of function rather than sequence. The only disclosed compound in *Ex parte Maizel* was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in *Ex parte Maizel* urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the claims encompassed an unduly broad number of compounds. Such is the instant situation because the claims simply recite probes which are functionally capable of forming a hybrid with *T. vaginalis*, but not with *T. tenax*.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Art Unit: 1645

3. Claims 1-19, 21-38 and 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "stringent hybridization conditions." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. Stringency is determined by the physical and chemical conditions under which the hybridization takes place as well as subsequent washing steps. However, without some guidance as to the physical and chemical conditions of the hybridization as well as that of the wash step which are deemed "stringent" as opposed to conditions considered non-stringent, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

4. Claims 1-19, 21-38 and 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the use of the phrase "derived from." Since it is unclear if the nucleic acid is undergoing any kind of chemical modification as implied by the recitation of "derived." Since it is unclear how the molecules are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase. As a suggestion, amendment of the claims to recite "obtained from" will be sufficient to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-19, and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mayta et al.

The claims are directed to a detection probe for use determining the presence of *Trichomonas vaginalis* in a test sample, said probe being up to 100 bases in length and comprising a target binding region which forms a hybrid stable for detection with a sequence contained within a first target sequence selected from the group consisting of SEQ ID NO: 1-4 under stringent hybridization conditions, wherein said probe does not form a hybrid stable for detection with nucleic acid derived from *Trichomonas tenax* under said conditions.

Mayta et al (Journal of Clinical Microbiology Vol. 38, No. 7, pp 2683-2687, July 2000) discloses of probe Tv2, an oligonucleotide of 21 bases that detects the presence of *T. vaginalis* in a sample but does not form a hybrid with other species of *Trichomonas*. (See page 2684). Furthermore the probe disclosed by Mayta et al is a 100% match with 21 consecutive bases of SEQ ID NO: 3 of the instant invention.

Accordingly, the probe disclosed by Mayta et al is deemed to anticipate the claimed invention.

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark Navarro
Primary Examiner
November 7, 2006